GAU 1647

AMENDMENT TRANSMITTAL LETTER (Small Entity)

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PATENT & TRADEMARK OFFICE

Applicant(s): Lee and Dams			Docket No. PENN-0583
Serial No. 09/297,877	Filing Date June 28, 1999	Examiner B. Bunner	Group Art Unit 1647

Invention: **SCREENING FOR MODULATORS OF AMYLOID PROCESSING**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

- ☒ Small Entity status of this application has been established under 37 CFR 1.27 by a verified statement previously submitted.
- ☐ A verified statement to establish Small Entity status under 37 FR 1.27 is enclosed.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST # PREV. PAID FOR		NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	3	-	20	=	0	x $9.00	$0.00
INDEP. CLAIMS	1	-	3	=	0	x $40.00	$0.00
Multiple Dependent Claims (check if applicable) ☐							$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT							$0.00

- ☒ No additional fee is required for amendment.
- ☐ Please charge Deposit Account No. _____ in the amount of _____
  A duplicate copy of this sheet is enclosed.
- ☐ A check in the amount of _____ to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. **50-1619**
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  - ☒ Any additional filing fees required under 37 C.F.R. 1.16.
  - ☒ Any patent application processing fees under 37 CFR 1.17.

Jane Massey Licata
Signature

Dated: **April 13, 2001**

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I certify that this document and fee is being deposited on **April 13, 2001** with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Signature of Person Mailing Correspondence

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Typed or Printed Name of Person Mailing Correspondence

cc:

DmT 4-19-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.:	**PENN-0583**
Inventors:	**Lee and Doms**
Serial No.:	**09/297,877**
Filing Date:	**June 28, 1999**
Examiner:	**B. Bunner**
Group Art Unit:	**1647**
Title:	**Screening for Modulators of Amyloid Processing**

I, **Jane Massey Licata**, Registration No. **32,257**, certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On this date: **April 13, 2001**

Jane Massey Licata

Jane Massey Licata, Registration No. **32,257**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Examiner Bunner:

REPLY TO RESTRICTION REQUIREMENT

This reply is to the Restriction Requirement mailed March 14, 2001 setting a one (1) month statutory period for response. Please enter the following remarks into the record.

REMARKS

Claims 1-3 are pending in the instant application. The claims have been subjected to a Restriction Requirement as follows:

Group I, claim 1, drawn to a method of identifying agents which increase or decrease processing of amyloid precursor protein

into amyloid β peptides found in neuritic plaques and vascular deposits that accumulate in the brains of patients with Alzheimer's disease comprising contacting NT2N cells with the compound and measuring the levels of amyloid β peptides formed in the endoplasmic reticulum of the cells.

Group II, claim 2, drawn to a method of diagnosing Alzheimer's disease in a patient comprising detecting in the patient an agent identified to increase processing of amyloid precursor protein into amyloid β peptides found in neuritic plaques and vascular deposits.

Group III, claim 3, drawn to a method of inhibiting processing of amyloid precursor protein in the brain of patients with Alzheimer's disease comprising administering to the patient an agent which decreases processing of amyloid precursor protein into amyloid β peptides.

The Examiner suggests that these Groups as set forth above do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features. The Examiner suggests that Werkin et al. teaches a method of contacting NT2N cells with retinoic acid, which increases or decreases amyloid precursor protein processing thus rendering claim 1 not novel. The Examiner further suggests that the technical feature of claim 1 is not a

contribution over the prior art and is not considered a special technical feature under PCT Rule 13.1. Applicants respectfully traverse this restriction requirement.

As stated in MPEP § 1850, the Office should permit retention in the same application for searching and/or preliminary examination claims to categories which meet the unity of invention requirements of PCT Rule 13.2.

Unity of invention exists when there is a technical relationship among the claimed inventions involving one or more special technical features. See MPEP § 1850. The term "special technical feature" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole makes over the prior art. As also taught in MPEP § 1850, unity of invention has to be considered in the first place only in relation to the independent claims and not the dependent claims.

Thus, restriction between Groups I, II and III, which is based at least in part upon differences in dependent claims is inappropriate. Further, the "special technical feature" or contribution which all the diagnostic methods share and which is not taught in the prior art relates to the concept of novel β-secretase pathways which produce the amyloid β peptides found in

neuritic plaques and vascular deposits that accumulate in the brains of patients with Alzheimer's disease. Accordingly, each of the claims is related to the identification of agents which modulate formation of amyloid β peptides found in the endoplasmic reticulum of Alzheimer's patients. The technical relationship shared between Groups I, II and III clearly meets the unity of invention requirements of PCT Article 13.2. It is therefore respectfully requested that this restriction requirement, with respect to Groups I, II and III, be withdrawn.

However, in an earnest effort to be completely responsive, Applicants elect with traverse Group II, claim 2, drawn to a method of diagnosing Alzheimer's disease in a patient comprising detecting in the patient an agent identified to increase processing of amyloid precursor protein into amyloid β peptides found in neuritic plaques and vascular deposits that accumulate in brains of patients with Alzheimer's disease in accordance with the method of claim 1.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and removal of the restriction requirement with respect to the pending claims is earnestly solicited.

Respectfully submitted,

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Date: April 13, 2001

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